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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,779	02/07/2002	Samuel Achilefu	MRD/ 75	4257

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EXAMINER

JONES, DAMERON LEVEST

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 01/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/071,779

Applicant(s)

ACHILEFU ET AL.

Examiner

D. L. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-22 is/are pending in the application.
- 4a) Of the above claim(s) 10-14 and 20-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8,9 and 15-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

ACKNOWLEDGMENTS

1. The Examiner acknowledge receipt of Paper No. 5, filed 10/14/03, wherein the specification was amended; claims 1-7 were canceled; and claim 8 was amended.

Note: claims 8-22 are pending.

RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS

2. The Applicant's arguments filed 10/14/03 (Paper No. 5) to the rejection of claims 8, 15-17, and 19 made by the Examiner under 35 USC 103 and/or 112 have been fully considered and deemed persuasive-in-part for the reasons set forth below.

112 Rejections

The 112 rejections are WITHDRAWN for reasons of record in Applicant's response.

103 Rejection

The rejection of claims 8, 15-17, and 19 under 35 USC 103(a) as being unpatentable over Turner et al (US Patent No. 6,329,531) is MAINTAINED for reasons of record in the office action mailed 7/14/03, Paper No. 4, and those set forth below.

Applicant assert that the methods are distinguished over the cited prior art because the method claims of the instant invention are directed to **simultaneous** diagnosis and therapy whereas Turner et al disclose a diagnostic method.

First, it should be noted that Applicant's claim as written is ambiguous for the reasons set forth below. However, if Applicant's claims are directed to simultaneous diagnosing and therapy, the claims are still not distinguished over the cited prior art.

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Specifically, independent claim 8 comprises the steps of administering to an individual a composition of Formula 4 and thereafter performing said procedure. Thus, since both Applicant and Turner et al administer compositions of Formula 4 and perform a procedure thereafter, the therapy that comes from administering the composition is inherent. In other words, the claim as written if directed to a simultaneous procedure lack therapeutic steps. Hence, the preamble in regards to the therapy does not add any additional limitations to the claims absent a therapeutic step.

Restriction Comments/Concerns

Applicant asserts that the instant invention is directed to simultaneously performing diagnostic and therapy. In addition, it is asserted that it is improper for the Examiner to fragment the invention and force Applicant to elect an invention from within a single claim (see the Examiner's response under the new grounds of rejection below).

WITHDRAWN CLAIMS

3. Claims 10-14 and 20-22 and 11 are withdrawn from further consideration by the Examiner for reasons of record in the office action filed 7/14/03, Paper No. 4.

NEW GROUNDS OF REJECTION**112 Second Paragraph Rejections**

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claims 8, 9, and 15-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims as written are ambiguous because one cannot readily ascertain if the invention is directed to simultaneous methods of diagnosis and therapy or individual methods.

(1) If Applicant's claims are directed to simultaneously performing diagnostic and therapeutic procedures what procedure is Applicant referring to in the last line of claim 8? Claim 8 comprises the steps of administering a composition of Formula 4 and "thereafter performing said procedure". It should be noted that 'procedure' is single, not plural. Also, it should be noted that the claim does not include the term 'simultaneously'. For example, 'a method of simultaneously performing a diagnostic and therapeutic procedure'. In addition, it should be noted that the claim does not list any steps directed to therapy. Furthermore, the claim as written does not require the presence of both a therapeutic or targeting agent be present for diagnosis. For example, if the variables are defined as follows, then no therapeutic or diagnostic agent is present: Y1, Y2, Z1, and Z2 = H; K1 and K2 = alkyl; X1 and X2 = single bond; R10-R13 and R18-R31 = H; W1 and W2 are independently CR10R11, O, NR12, S, or Se; a1 and b1 are independently 0-5; R14-R17 = H; a and b are independently 1-20; b and d are independently 1-100; A1 = single/double bond; and B1, C1, and D1 are independently O, S, Se, P, CR10R11, alkyl, NR12, and C=O or A1, B1, C1, and D1 together form a 6- to 12-membered heterocyclic ring. In this instance, there is no

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diagnostic or therapeutic agent present. Also, it is noted that there is not proviso, for example, which require the variables to be selected such that the composition has the two need components for the diagnostic and therapeutic procedures.

(2) At the time the Examiner called Applicant regarding the restriction requirement, Applicant elected to prosecute Group II, directed to a diagnostic procedure. It was not disclosed that the claims were intended to read on simultaneous procedures (see also the 'Interview Summary' on 7/8/03). Furthermore, in regards to the presence of the term 'and' (claim 8, lines 1-2) indicating that the procedures are simultaneous, Applicant's attention is directed to the following. Claim 8, lines 5-6, disclose the phrase 'W1 and W2 may be the same or different and are selected from the group consisting of CR10R11, O, NR12, S, **and** Se'. Note that the term 'and' also links Applicant's phrase. However, it is clear that each of W1 and W2 individually cannot have more than one meaning. In other words, the phrase is interpreted as if it had the term 'or' inserted between each variable definition. Likewise, the phrase 'diagnostic and therapeutic' may be interpreted.

(3) The specification, pages 15-16, bridging paragraph, discloses that the compositions for diagnostic uses are administered in doses effective to achieve the desired effect. The paragraph further discloses that the compositions may be administered to a patient and the patient subjected to diagnostic imaging, **and/or** therapeutic procedures. Hence, a skilled practitioner in the art would recognize that the compositions may be administered for diagnostic purposes, therapeutic purposes, or both diagnostic and therapeutic purposes.

Applicant is respectfully requested to clarify the claims in order that one may readily ascertain what is being claimed.

COMMENTS/NOTES

6. It should be noted that no prior art has been cited against claims 9 and 28 in regards to the elected species ONLY. However, Applicant must address and overcome the 112 rejections above regarding the claims.

Note: The claims are distinguished over the prior art of record for reasons of record in the office action mailed 7/14/03, Paper No. 4.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (703) 308-4640. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (703) 308 - 2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



D. L. Jones
Primary Examiner
Art Unit 1616

January 22, 2004